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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,463	07/19/2002	Neil R. Anderson	29342/36539A	6929

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EXAMINER

BERNHARDT, EMILY B

ART UNIT PAPER NUMBER

1624

DATE MAILED: 01/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,463	ANDERSON ET AL.	
	Examiner	Art Unit	
	Emily Bernhardt	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 20-22 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-9, 14 -16 is/are allowed.
- 6) ☒ Claim(s) 10-13 and 20-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>08052002</u> . | 6) <input type="checkbox"/> Other: _____ |

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required. Note that the cover sheet from the corresponding WO publication is not considered part of the instant disclosure.

Claims 10-13, 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. It is not seen how claim 11 further limits the scope of claim 10 since the same pharmacokinetic parameters are recited in both claims. It is recognized that an “or” follows the C_{\max} definition in claim 10 vs an “and” in claim 11. If this is really intended in claim 10 how then does claim 11 further limit?

2. With further regard to the pharmacokinetic parameters recited in claims 10-11 and in 12 and 20-22, the scope of intended compounds is not clear. Data on p.27 of the specification would only include 2 of the 3 particle sizes for the C_{\max} range vs. all the 3 sizes for the AUC range recited. Thus the 2 sets of limitations give a varying scope unless one is further limiting. Clarification is needed.

3. How does claim 10 differ from claim 5, the latter which embraces the uppermost limit of particle size described as the instant invention? The same would apply to claims 7-9 vs. 20-22.

4. The term "and bioequivalent compositions thereof" in claim 13 requires clarification for more than one reason. The claim language literally recites an additional active ingredient together with that already recited in part (a) of the claim. Additionally, are applicants claiming the same compound only having a different particle size as the bioequivalent composition or an entirely different compound? If the latter, specification provides no guidance as to structural makeup. The definition given in the specification does not help ascertain intended scope.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Butler (WO'131). The WO and US equivalent has been cited by applicants. Claim 12 reads on the same compound as described in Butler which has been formulated as a coprecipitate to increase its bioavailability. See compound A formulations on p.14-15. Said formulations reads on the instant composition claim which recites no particular form of the active ingredient- i.e. includes the free form as well as the drug in embedded form. While instant claim recites certain range of AUC and C_{max}


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values, no evidence is seen in the file that this prior art composition inherently lacks the characteristics recited herein. Note In re Fitzgerald 205 USPQ 594; In re Grose 210 USPQ 57 which are on point.

Claims 1-9,14-16 are allowed over the art of record and from a search in the pertinent art area which lacks a teaching of modifying instant compounds to a narrow range of particle sizes.

Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The new fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.


EMILY BERNHARDT
PRIMARY EXAMINER
GROUP 1600